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09/915,494	07/25/2001	Robert Thomas Hudak	AC-00127.P.1	6752

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EXAMINER
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COUNTS, GARY W

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 10/22/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/915,494

Applicant(s)

HUDAK, ROBERT THOMAS

Examiner

Gary W. Counts

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 28 May 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-59 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-59 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 & 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Information Disclosure Statement***

The [www.3dl.net/drugtests.html](http://www.3dl.net/drugtests.html) reference and the [www.health.org/workplace/urinebook.htm](http://www.health.org/workplace/urinebook.htm) reference have not been considered because there is no date of publication listed on the IDS for the references and therefore, the relevance of the references cannot be determined for prior art purposes.

### ***Specification***

The disclosure is objected to because of the following informalities: On page 1 of the specification under the title Brief Description of the Figures. The applicant discloses that figure 2 represents the valve 200 in a series of longitudinal cross sections.

However, Figure 2 comprises Figures A-F. It is recommended to insert --(A-F)-- after the disclosure Fig. 2.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 1, part (a) the recitation "capable of" is vague and indefinite. The recitation is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138.

Claim 1, part (b) the recitation "capable of" is vague and indefinite. The recitation is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138.

Claim 1 part (c) "is capable of" is vague and indefinite. The recitation is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138. See also deficiencies found in claims 35, 37-39

Claim 7 is vague and indefinite because of the use of an acronym: i.e. PSI. Although the term may have art recognized meanings, it is unclear if applicant intends to claim the prior art definition. The term should be defined in its first instance.

Claim 8 the recitation "can hold" is vague and indefinite. Does the chamber hold a specimen between about 0.0001 milliliter and about 1,000 milliliters or not?

Claim 13 the recitation "optionally" is vague and indefinite. The recitation is not a positive limitation.

Claim 13 the recitation "substantially planar surface" is vague and indefinite. The term "substantially" is a relative term, which renders the claim indefinite. There is no definition or guidance in the specification for the term. It is unclear what is considered to be substantially planar.

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Claim 15 the recitation "snugly" is vague and indefinite. The term "snugly" is a relative term which renders the claim indefinite. There is no definition or guidance provided for the term in the specification. It is unclear what is considered to be snugly.

Claim 20 the recitation "substantially cylindrical" is vague and indefinite. The term "substantially" is a relative term which renders the claim indefinite. There is no definition or guidance in the specification for the term. It is unclear what is considered to be substantially cylindrical.

Claim 29 is vague and indefinite because it is unclear what applicant intends. The chamber and the reservoir comprise a single unit of what? Does this mean the chamber is the reservoir?

Claim 30 is vague and indefinite because it is unclear what applicant intends.

Claim 44 is vague and indefinite because the preamble of the claim does not correlate with the body of the claim. The preamble of the claim is directed to a method of detecting an analyte of interest in a specimen. However, there is no positive recitation in the body of the claim in which an analyte is detected. There are only methods steps of transferring a specimen to a testing device.

Claim 44 is vague and indefinite because it is confusing if steps 1-4 are individual steps or if they are referring back to claims 1-4. It is recommended to change "1-4" to --a-d--.

Claim 44 the recitation "optionally" is vague and indefinite. The recitation is not a positive recitation. Further, it is unclear if the specimen is not in the reservoir how is the analyte tested?

Claim 48 the recitation "can be" is vague and indefinite. The recitation is not a positive limitation. Is a temperature sensing device examined or not? And if so, it is unclear what relationship exists between this examination and detecting the analyte.

Claim 58 the recitation "can be" is vague and indefinite. The recitation is not a positive limitation. See also deficiency found in claim 59.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 2, 4, 13, 15, 16, 17, 19, 20, 22, 26, 27, 29, 31, 33-39, 42, 44-46, 49 and 51-56 are rejected under 35 U.S.C. 102(e) as being anticipated by Cui et al (US 6,576,193).

Cui et al disclose devices and methods for collecting a fluid specimen and testing the fluid specimen for detecting the presence of a particular analyte. Cui et al disclose a first compartment (chamber) for fluid collection. Cui et al disclose a second compartment (reservoir) for receiving a portion of the fluid. Cui et al disclose a valve interposed between the first compartment and the second compartment (Fig. 1 and Fig. 9). Cui et al disclose that the first compartment (chamber) comprises a lid for sealing the fluid within the first compartment (col. 4, lines 1-9). Cui et al disclose that the

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second compartment is spaced to allow receipt of a test device such as a test strip (col 5). Cui et al disclose that test strips using immunoassays or chemical patches can be used to determine an analyte of interest (col 7, lines 37-60). Cui et al disclose that the fluid sample can be blood, plasma, serum or urine (col. 7, lines 1-20).

5. Claims 1, 11, 14, 16, 17, 19, 20, 22, 30, 32-46, 49, and 51-57 are rejected under 35 U.S.C. 102(e) as being anticipated by Hudak et al (US 6,565,808).

Hudak et al disclose a sample receiving chamber and a test platform (reservoir). Hudak et al disclose a valve functionally interposed between the chamber and test platform (reservoir) (Fig. 1, item 20).

6. Claims 1-4, 11, 14, 16, 17, 19, 21-23, 28, 29, 31, 33, 34, 39, 40, 44-47, 49, and 51-54 rejected under 35 U.S.C. 102(e) as being anticipated by Guirguis et al (US 6,277,646).

Guirguis et al disclose a device and method for determining an analyte of interest. Guirguis et al disclose a collection chamber, isolating chamber and a testing chamber (reservoir) which comprises a test strip. Guirguis et al disclose a fluid releasing element (valve) interposed between the collection chamber, isolation chamber and test chamber (reservoir). Guirguis et al disclose that the fluid releasing element (valve) opens the isolation chamber and releases fluid from the isolating chamber allowing fluid to be directed to the test chamber (reservoir) (col 7).

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 3, 5, 7, 8, 18, 47 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cui et al in view of Nelson et al (US 5,115,934).

See above for teachings of Cui et al.

Cui et al differ from the instant invention in failing to teach the seal is tamper resistant.

Nelson et al disclose a tamper resistant seal for containers. Nelson et al disclose that this tamper resistant seal provides for a cover that is secure but yet may be easily removed providing access to the container.

It would have been obvious to one of ordinary skill in the art to incorporate a tamper resistant seal as taught by Nelson et al into the device and method of Cui et al because Nelson et al shows that this tamper resistant seal provides for a cover that is secure but yet may be easily removed providing access to the container.

With respect to the specimen volume as recited in the instant claims, the optimum specimen volume can be determined by routine experimentation and thus would have been



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obvious to one of ordinary skill in the art. Further, it has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation." Application of Aller, 220 F.2d 454,456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation ." Id. At 458,105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Application of Boesch, 617 F.2d 272,276, 205 USPQ 215, 218-219 (C.C.P.A. 1980).

10. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cui et al in view of Alley (US 2002/00446614).

See above for teachings of Cui et al.

Cui et al differ from the instant invention in failing to teach the seal comprises at least one O-ring.

Alley discloses a seal comprising an O-ring. Alley discloses that the use of this O-ring provides a means of securing the seal to the container. Furthermore, the use of O-rings in a seal is well known in the art.

It would have been obvious to one of ordinary skill in the art to incorporate an O-ring as taught by Alley into the device of Cui et al because Alley shows that the use of this O-ring provides a means of securing the seal to the container.

11. Claims 9, 32, 43, 48 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cui et al in view of Ehrenkranz (US 4,769,215).

See above for teachings of Cui et al.

Cui et al differ from the instant invention in failing to teach the chamber comprises a temperature-sensing device.

Ehrenkranz discloses a urine collection apparatus, which comprises a thermometer within the device. Ehrenkranz discloses that the use of this thermometer provides a means for determining the freshness of the urine and also provides an alternative for physical examination (col. 5, lines 19-37 and abstract).

It would have been obvious to one of ordinary skill in the art to incorporate the thermometer as taught by Ehrenkranz into the device of Cui et al because Ehrenkranz shows that the use of this thermometer provides a means for determining the freshness of urine and also provides an alternative for physical examination.

With respect to the recitation "wherein said reservoir is removable from said chamber" as recited in the instant claims. Cui et al disclose the claimed invention except for teaching the reservoir is removable from the chamber. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the chamber and reservoir as separate parts, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177, 179.

12. Claim 10-12, 14, 58 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cui et al in view of Kantner (US 4,211,749).

See above for teachings of Cui et al.

Cui et al differ from the instant invention in failing to teach the chamber comprises a label on which to record data pertaining to the specimen. Cui et al also fails to teach the

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chamber is tapered. Cui et al also fails to specifically teach that the container comprises plastic.

Kantner disclose a urine container, which comprises an informative label containing important information relative to the patient in a manner ensuring that the label is not lost. Furthermore, it is well known in the art to place a label on a container to record patient information on the container. Kantner et al also disclose the container is tapered. Kantner disclose that this provides nesting of successive containers on top of one another. Kantner also teach that the container is made of plastic which allows for a successful and cheap material (col. 15, lines 1-14).

It would have been obvious to incorporate a label such as taught by Kantner et al in the device of Cui et al because Kantner shows that the use of such a label provides for important information relative to the patient in a manner ensuring that the label is not lost. It also would have been obvious to one of ordinary skill in the art to taper the device of Cui et al such as taught by Kantner because Kantner discloses that this provides nesting of successive containers on top of one another. It also would have been obvious to one of ordinary skill in the art to incorporate plastic as taught by Kantner into the device of Cui et al because Kantner teaches that the plastic material allows for successful and cheap material in a urine container.

13. Claims 21, 24, 25 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cui et al in view of Mitsumaki et al (US 4,680,270) and Godin et al (US 3,991,055).

See above for teachings of Cui et al.

Cui et al differ from the instant invention in failing to teach the valve comprises a piston configuration. Cui et al also fail to teach that the valve comprises an O-ring.

Mitsumaki et al teaches the equivalence of rotary valves and slide valves in the art.

Godin et al teach a sliding valve which comprises a piston and O-ring for the transfer of liquid sample. Godin et al disclose that the use of such a valve provides for the operator to choose between segmenting operation on a sample or a prediluted sample without using separate valving and considerable increase in fluid lines.

It would have been obvious to one of ordinary skill in the art to incorporate slide valves as taught by Godin et al into the device of Cui et al because Mitsumaki et al shows that it is known in the art to use slide valves instead of rotating valves and because Godin et al shows that the use of such a valve provides for the operator to choose between segmenting operation on a sample or a prediluted sample without using separate valving and considerable increase in fluid lines.

### ***Double Patenting***

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 1-20 and 22-59 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-62 of copending Application No. 10/211,199. Although the conflicting claims are not identical, they are not patentably distinct from each other because one skilled in the art would recognize that the narrow claims of the device concerning the valve in application 10/211,199 would encompass the more broad claims of the device in application 09/915,494.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (703) 305-1444. The examiner can normally be reached on M-F 8:00 - 4:30.

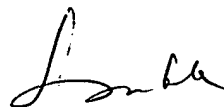
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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Gary W. Counts  
Examiner  
Art Unit 1641  
October 16, 2003



LONG V. LE  
SUPERVISORY PATENT EXAMINER  
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10/16/03